II. LISTING OF THE CLAIMS

The claims have not been amended. This listing of claims is being provided for the Examiner's convenience.

Claim 1.(Previously presented) A solid controlled release oral dosage form, comprising,

a therapeutically effective amount of tramadol or a pharmaceutically acceptable salt thereof incorporated into a normal release matrix,

said matrix overcoated with a controlled release coating comprising a polymethacrylate or a water insoluble cellulose,

said dosage form providing a therapeutic effect for at least about 24 hours.

Claims 2-41 (Cancelled)

Claim 42.(Previously presented) The controlled release dosage form as claimed in claim 1, wherein said controlled release coating comprises a polymethacrylate.

Claim 43.(Previously presented) The controlled release dosage form as claimed in claim 1, wherein said controlled release coating comprises a water insoluble cellulose.

Claim 44.(Previously presented) The controlled release dosage form as claimed in claim 42, wherein said controlled release coating further comprises a water soluble cellulose.

Claim 45.(Previously presented) The controlled release dosage form as claimed in claim 43, wherein said controlled release coating further comprises a polyvinylpyrrolidone.

Claim 46.(Previously presented) The controlled release dosage form as claimed in claim 1, containing from about 50 to 800mg of tramadol or a pharmaceutically acceptable salt thereof, calculated as the hydrochloride salt.

Claim 47.(Previously presented) The controlled release dosage form as claimed in claim 1, having a dissolution rate in-vitro when measured using the Ph. Eur. Paddle Method at

100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 0 to about 50% tramadol released after 1 hour; from about 0 to about 75% tramadol released after 2 hours; from about 10 to about 95% tramadol released after 4 hours; from about 35 to about 100% after 8 hours; from about 55 to about 100% tramadol released after 12 hours; from about 70 to about 100% tramadol released after 16 hours; and greater than 90% tramadol released after 24 hours, by weight.

Claim 48.(Previously presented) The controlled release dosage form as claimed in claim 1, having a dissolution rate in-vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 0 to about 30% tramadol released after 1 hour; from about 0 to about 40% tramadol released after 2 hours; from about 3 to about 55% tramadol released after 4 hours; from about 10 to about 65% after 8 hours; from about 20 to about 75% tramadol released after 12 hours; from about 30 to about 88% tramadol released after 16 hours; from about 50 to about 100% tramadol released after 24 hours and greater than 80% tramadol released after 36 hours, by weight.

Claim 49.(Previously presented) The controlled release dosage form as claimed in claim 1, having a dissolution rate in-vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 15 to about 25% tramadol released after 1 hour; from about 25 to about 35% tramadol released after 2 hours; from about 30 to about 45% tramadol released after 4 hours; from about 40 to about 60% after 8 hours; from about 55 to about 70% tramadol released after 12 hours; and from about 60 to about 75% tramadol released after 16 hours, by weight.

Claim 50.(Previously presented) The dosage form according to claim 1, which provides a t_{max} from about 3 to about 6 hours.

Claim 51.(Previously presented) The dosage form according to claim 1, which provides a W_{50} from about 10 to about 33 hours.

Claims 52-62. (Cancelled)

63. (New) The dosage form according to claim 43. wherein said water insoluble cellulose comprises ethylcellulose.

64. (New) The dosage form of claim 1, comprising 100 mg tramadol hydrochloride.

65. (New) The dosage form of claim 1, comprising 200 mg tramadol hydrochloride.

66. (New) The dosage form of claim 1, comprising 300 mg tramadol hydrochloride.

67. (New) The dosage form of claim 1, comprising 400 mg tramadol hydrochloride.

68. (New) The dosage form of claim 1, comprising 600 mg tramadol hydrochloride.

This response is being submitted within 30 (thirty) from the date of the Notice of Non-Compliant Amendment. Accordingly, no fee is believed due. If it is determined that any fees are due, Commissioner is hereby authorized to charge any deficiencies to Attorney Deposit Account No. 50-0552.

Respectfully submitted,
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